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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,938	06/25/2001	Graham P. Allaway	50875-DA/JPW/SHS	9272

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EXAMINER	
PENG, BO	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
09/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/888,938	ALLAWAY ET AL.	
	Examiner	Art Unit	
	BO PENG	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/15/08 & 5/8/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51 and 57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/15/08 & 2/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is in response to the amendment received September 15, 2008, and May 8, 2009. Claims 51 and 57 are pending and under examination in this Office action.

Claim Rejections - 35 USC § 112, first paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. (**Prior rejection-maintained**) The rejection of Claims 51 and 57, as failing to comply with the written description requirement **is maintained** for the reason of record.

In response to Applicant's arguments:

4. Applicant's argument: The Court of Appeals for the Federal Circuit specifically addressed the question of adequate written description in the context of a claimed antibody in *Noelle v. Lederman,* 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (2004). In *Noelle,* the Court stated that disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository provides an adequate written description of an antibody claimed by its affinity to that antigen. Applicant argues that the CCR5 antigen to which the antibody binds is well characterized. Raising antibodies against a known antigen was routine at the time of applicants' invention. The specification discloses how to obtain the sequence of CCR5, and how to make the claimed antibodies to CCR5.

5. Examiner's response: This argument is not convincing because *Noelle v. Lederman* does not support Applicant's argument. According to *Noelle v. Lederman,* in order to provide an adequate written description of an antibody, the antigen should be fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository by its affinity to that antigen. In the present case, Claims 51 and 57 lack adequate descriptive support for the claimed genus of a monoclonal antibody that has the ability to both bind to CCR5 and inhibit HIV fusion to cells because the specification fails to fully characterize the epitope(s) (or antigen) on CCR5 that are involved in HIV fusion to CD4.

6. It is noted that the structure of an antigen is not only characterized by its primary sequence, but also by its conformational structure. Although the sequence of CCR5 was known at the time the invention was filed, the art indicated that conformational structure(s) of CCR5 that are associated with HIV fusion to CD4 are not full characterized. Therefore, there is a lack of a general correlation between the antibody binding to CCR5 and inhibiting fusion of HIV. See e.g., Lee *et al*., J. Biochemical Chem (Exhibit 2, submitted by Applicant on December 10, 2007). The previous Office action has provided a detailed discussion regarding Lee's teaching in Para 8. Importantly, the instant specification has failed to provide any guidance regarding the specific region(s) or epitopes on CCR5 responsible for HIV binding and entry, and has failed to present any working examples showing any specific monoclonal antibody that both binds to CCR5 and inhibits HIV fusion to CD4. Because of the lack of knowledge of specific epitope(s) on CCR5 that are required for HIV entry either in the prior art or the specification, one of ordinary skill in the art cannot envision which monoclonal antibodies to CCR5 can inhibit HIV fusion, even when accompanied by a method of making a monoclonal antibody to CCR5. Accordingly, it is deemed

that the specification fails to provide adequate written description for a genus of CCR5 antibodies that can inhibit HIV fusion. The rejection is therefore maintained.

Claim Rejections - 35 USC § 102/103

7. (**Prior rejection-withdrawn**) The rejection of Claims 51 and 57 under 35 U.S.C. § 102(e) as anticipated by, or alternatively, under 35 U.S.C. § 103 as obvious over Li *et al*. (US 6,759,519), as evidenced by Wu (US 6,528,265), **is withdrawn** in view of Applicants' argument. Applicant's arguments, see Remarks, filed on September 15, 2008, have been fully considered and are persuasive. The rejection has been withdrawn.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering the patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c)

and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. (**Prior rejection-maintained**) The rejection of Claims 51 and 57 under 35 U.S.C. 103(a) as being unpatentable over Cocchi *et al* (1995, Science Vol. 207, p.1811-1815, cited in IDS) and Samson *et al*. (1996, Biochemistry Vol. 35, p.3362-7, cited in IDS), both in view of Berger (US 6,197,578), **is maintained** for the reasons of record.

In response to Applicant's arguments:

10. Applicant presents the same argument as before, that the claimed antibody relates to CCR5 which is a co-receptor for macrophage-tropic HIV strains, whereas CXCR4 is a receptor for T-cell tropic HIV strains. There is no basis for the assertion that there is a "reasonable expectation of success" because the prior art discloses a different antibody against a different receptor that blocks fusion of a different HIV strain.

11. Examiner's response: This argument has been found not persuasive. Because both chemokine receptors CXCR4 and CCR5 are expressed on the surface of CD4 cells, one of ordinary skill in the art would recognize that the prior art anti-CXCR4 antibody against HIV fusion to CD4+ cells and the claimed anti-CCR5 antibody against HIV fusion to CD4 cells are functional equivalents although they target different chemokine receptors on CD4 cells.

12. Since Berger has shown that an antibody against chemokine receptor CXCR4 can inhibit HIV fusion to CD4+ T cells, it would have been obvious to one of skill in the art to substitute another antibody against other chemokine receptors used by HIV for entry into a CD4 cell, such as CCR5, to achieve the predictable result of inhibiting HIV fusion to a CD4 cells.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. (**Prior rejection- maintained-updated**) The rejection of Claims 51 and 57 under the non-statutory double patenting over Claims 1-9 and 33-38 of US Pat 7,122,185 (Application No. 10/371,483) **is maintained**.

14. Applicant acknowledges the rejection and does not wish to prematurely respond.

15. (**Prior rejection- maintained-updated**) The rejection of Claims 51 and 57 on the grounds of non-statutory obviousness-type double patenting as being unpatentable over Claims 78-97 of co-pending Application **11/804,746** ('746) and Claims 78-107 of co-pending Application **11/805,573** ('573), is maintained.

16. Applicant acknowledges the rejection and does not wish to prematurely respond.

Remarks

17. No claims are allowed. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The Examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Primary Examiner, Art Unit 1648